IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

HULSMANN et al.

Examiner: WEBMAN, Edward J.

Serial No.: 09/937,302

Group Art Unit: 1617

Filed: 3/27/2002

Title: **PHARMACEUTICAL COMPOSITION CONTAINING AN EXTRUSION ADDITIVE**

REPLY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on July 19, 2006, please consider the following remarks.

The First Rejection Under 35 USC § 103

Claims 1, 4, 6, 10-13, 15, 17, 19-20, and 22-32 are rejected over Zettler in view of Budavari.

The Office Action reconstructs applicants' invention from various large lists from Zettler by picking and choosing the ingredients by following applicants' claims as a roadmap. Without applicants' claim, nothing in Zettler provides the motivation to prepare applicants' invention. This is apparent even from the rejection itself which points to the following locations in Zettler's disclosure to piece together applicants' invention: abstract, column 3, line 48, column 4, lines 44-47, column 6, line 2, column 5, lines 25-26 and column 8, line 64. Without motivation to do so, one of ordinary skill in the art would not have been led to the selections necessary that are

scattered throughout Zettler's disclosure to make the present invention. As such, there is no obviousness.

Budavari teaches additional active ingredients, but does not overcome the deficiencies of the primary reference.

The Rejection Under 35 USC § 102

Meignant is alleged to anticipate claims 1, 4, 6, 13, 17, 19-20, 22-24, and 26-31.

Meignant does not teach an extrudate as pointed out in the last reply, and thus, it does not anticipate. Nevertheless, the anticipation rejection is maintained without comment on this issue.

Additionally, Meignant also teaches that the estradiol is micronized. The Office Action alleges that this is merely a preference. At a single location in Meignant, the generic disclosure states that the 17β-estradiol is "free or vectorized micronized." However, for anticipation it is not adequate that the broad disclosure of the reference at a single location state something generically. See *In re Ruschig*, 343 F.2d 965, 145 USPQ 282 (C.C.P.A. 1965), where the court found that the broad disclosure of a reference with no guidance to the invention claimed was too broad to anticipate. Additionally, the Office Action alleges that the "micronized" feature of the active ingredient(s) is a process limitation. Applicants disagree because a micronized product itself is different in size from a non-micronized product. As such, the claims are not anticipated.

The Second Rejection Under 35 USC § 103

Claims 1, 4, 6, 8, 13, 17, 19-20, 22-24 and 26-31 are rejected over Rosenberg.

The Office Action points to various lists in the disclosure of Rosenberg and alleges that it would have been obvious to make selections to achieve applicants' invention. However, the

broad disclosure of possible ingredients for a composition for extrusion does not suggest applicant's claimed invention. For example, the examples of Rosenberg are directed to formulations (even when ignoring the differences in the active ingredients) that are not applicants' claimed invention and do not suggest it. Moreover, the claimed active ingredients herein are not even mentioned in Rosenberg. Rosenberg merely states that "all active ingredients which do not decompose under the conditions of melt extrusion" are suitable. However, such broad statements would not have prompted one of ordinary skill in the art to select applicants' claimed specific active ingredients, and then to use put it into a composition that is only broadly at most described by the disclosure of Rosenberg.

The Third Rejection Under 35 USC § 103

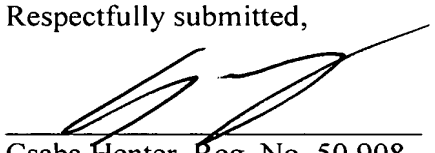
Claims 1, 4, 6-7, 9-13, 15, 17, 19-20, 22-24 and 26-32 are rejected over Appel.

Contrary to the allegations, Appel does not teach an extrudate form of a composition. Instead this reference teaches an invention where the core contains "a low solubility drug in the form of an amorphous solid dispersion." See column 2, lines 36-38. The formulation is nowhere described to be an extrudate. The term "extrusion" however is used in a different context by Appel. The reference's disclosure teaches a "non-dissolving and non-eroding coating surrounding the core, the coating controlling the influx of water to the core from an aqueous environment of use so as to cause drug release by extrusion of some or all of the core to the environment of use." The act of extruding an amorphous solid dispersion of a low solubility drug from an already otherwise prepared dosage form bears no relationship to Appel's "extrusion" phenomenon.

Additionally, the disclosure of Appel suffers from the same type of deficiencies as do the disclosures of Meignant, i.e., the various ingredients of the claimed compositions are scattered throughout the generic disclosure without guidance for their selection, and of Rosenberg, i.e., the claimed active ingredients are not even mentioned in the disclosure.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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